REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-6 and 12-13 are pending. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. Support for the claim amendments may be found, inter alia, in Example 1 of the specification. In addition, coagulated eggs are disclosed at several places in the specification (e.g., page 2, line 12, and page 3, line 12). In accordance with M.P.E.P. § 2173.05(i), a positively recited element presented as an alternative element may be explicitly excluded from the claims. Thus, no new matter is added by the claim amendments. Applicants also amend claim 1 to delete the term "naturally" to which the Office objected because the limitation is not required for patentability. Withdrawal of the rejection is requested.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-2, 4, 6 and 12 were rejected under Section 102(b) as allegedly anticipated by Charm et al. (U.S. Patent 5,354,663). Applicants traverse.

The claimed process requires contacting an uncoagulated egg sample with a test composition prior to inactivation of compounds that are capable of inhibiting growth of the test microorganism. In contrast, the '663 patent discloses a heating step that would coagulate an egg sample (see col. 3, lines 27-39) prior to contact with a test composition (see col. 3, lines 42-44). Thus, the cited document does not teach the claimed process which requires that inactivation be performed on an uncoagulated egg sample.

Claims 1-6 and 12-13 were rejected under Section 102(b) based on an allegedly "public use or sale of the invention" in the United States. Applicants traverse.

The Premi®Test for meat was publicly available more than one year prior to the earliest claimed priority date of this application (i.e., October 4, 1999), as evidenced by

Geijp et al. In addition, the Premi®Test for egg was disclosed February 2000, as shown by the attached inserts. As discussed in our previous response, the claimed process is not directed to Premi®Test itself, but rather testing an egg sample for antimicrobial residue using Premi®Test. The Premi®Test procedure for antimicrobial residue in egg was not publicly disclosed until after October 4, 1999. In contrast, the Premi®Test for antimicrobial residue in meat does not disclose the claimed process for an egg sample. There is no evidence of record that the "public use or sale of the invention" occurred in the United States. Therefore, there was no *prima facie* case made that the claimed process was publicly used or sold in the United States more than one year before the effective filing date of this application.

Withdrawal of the Section 102 rejections is requested.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. Obviousness can only be established by combining or modifying the prior art teachings to produce the claimed invention if there is some teaching, suggestion, or motivation to do so found in either the references themselves or in the knowledge generally available to a person of ordinary skill in the art. See, e.g., *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992). Evidence of the teaching, suggestion or motivation to combine or to modify references may come explicitly from statements in the prior art, the knowledge of a person of ordinary skill in the art or the nature of the problem to be solved, or may be implicit from the prior art as a whole rather than expressly stated in a reference. See *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999); *In re Kotzab*, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). Rigorous application of this requirement is the best defense against the subtle, but powerful, attraction of an obviousness analysis based on hindsight. See *Dembiczak* at 1617. Whether shown explicitly or implicitly, however, broad conclusory statements standing alone are not evidence because the showing must be clear and particular. See *id.* Finally, a

determination of prima facie obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claims 1-6 and 12 were rejected under Section 103(a) as allegedly unpatentable over Charm et al. (U.S. Patent 5,354,663). Applicants traverse.

This obviousness rejection fails for the same reasons as the anticipation rejection and the arguments presented above are incorporated by reference herein. In particular, heating an egg sample to a temperature sufficient to activate inhibiting substances would coagulate the egg sample prior to contact with a test composition. Therefore, the '663 patent teaches away from the claimed invention which requires contacting an egg sample with a test composition prior to coagulation. Further, the process disclosed in the '663 patent and the evidence of record fails to provide a reasonable expectation of success to contact the uncoagulated egg sample with a test composition prior to the heat inactivation of an inhibitor compound as recited in Applicants' claims. The Action also does not provide any evidence or reasoning that one of ordinary skill in the art would have been motivated to modify the disclosure of the '663 patent such that the egg sample is not coagulated prior to contact with the test composition. The necessary modifications to test eggs instead of milk are neither taught nor suggested in the '663 patent.

Withdrawal of the Section 103 rejection is requested.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 1-6 and 12-13 were rejected under Section 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants traverse.

The Office alleged that the inactivating step would encompass the antimicrobial residues that are to be detected. But the claimed process specifically avoids such an interpretation by reciting "without inactivating the antimicrobial residue to be detected" as a limitation. As shown by Examples 2-3 of the specification, the claimed invention is not inoperative as alleged by the Office. The heating inactivates the naturally-present inhibitor compound (see Example 2), but does not inactivate the antimicrobial residue that is the object of the invention (see Example 3). No evidence or technical reasoning was presented in the Action to contradict the objective truth of these teachings.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested.

35 U.S.C. 112 – Written Description

The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). But the Patent Office has the initial burden of presenting evidence or a reason why persons of ordinary skill in the art would not have recognized such a description of the claimed invention in the original disclosure. See *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Claim 1 was rejected under Section 112, first paragraph, because it was alleged that it contains "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicants traverse.

The Office objected to the phrase "any compound naturally present in the sample that is capable of inhibiting growth of the test microorganism leading to a false positive results absent said activating step . . ." as new matter. Support for this limitation is found, for example, in the paragraph bridging pages 1-2 of the specification. Therein Applicants teach inhibitor compounds (*i.e.*, antimicrobial substances), such as lysozyme, which are naturally present in eggs and show inhibitory activity against the test

microorganism leading to false positive results. Naturally-present inhibitor compounds are similarly described on page 3, lines 22-25, of the specification.

Withdrawal of the written description rejection made under Section 112, first paragraph, is requested.

35 U.S.C. 112 – Definiteness

Claims 1-6 and 12-13 were rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse.

The Office appeared to object to the term "naturally" that distinguishes inhibitor compounds that were not there due to the hand of man. Antibiotics (*i.e.*, antimicrobial residues) are administered to poultry (see page 1, lines 11-13, of the specification) and are not "naturally" present in eggs. It is believed that this limitation is not necessary for patentability and, therefore, it is deleted from the claims.

Applicants request withdrawal of the Section 112, second paragraph, rejection.

Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

Gary R. Tanigawa
Reg. No. 43,180

901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

DSM

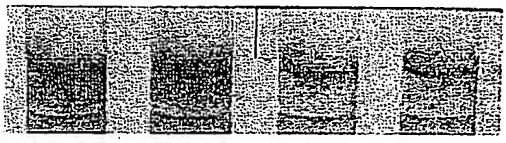
Premi®Test-egg

Broad spectrum screening test for detection of antimicrobial compounds in eggs.

A purple colour indicates a positive sample (the presence of anti-microbial compounds in the egg at or above the limit of detection).

Colour range of Premi®Test-egg

Positive | Negative



Who will use Premi® Test-egg?

Premi®Test-egg is suitable for use by egg processors, retailer and by inspection laboratories. It is ideal for use "on site" as no special laboratory equipment is needed to interpret the result. The rapidly obtained "yes/no" result is simply read by colour comparison.

Test principle

Premi®Test-egg is based on the inhibition of the growth of *Bacillus stearothermophilus*, a bacterium very sensitive to many antibiotics and sulpha compounds.
A standardised number of spores is imbedded in an agar medium with selected nutrients. These spores will remain viable for many months.
When placed in the Premi®Test heating block or a waterbath at 64°C the spores will germinate.

When no antibiotics are present, the bacteria will multiply and produce acids. This will be visible by a colour change from purple to yellow. When anti microbial compounds are present at or above above the detection level, no growth will occur and the colour will remain purple.

Test procedure

Simply make a hole of approximately 1-2 cm. in the egg that needs to be tested. Prick the egg-yolk and place the egg with the hole down on a bottle. After the egg is empty, close the bottle. Then homogenise the egg by shaking the bottle. Put a sample of 0.1 ml into the test and cover the ampoule with the provided sealing. Then incubate 10 minutes at 80°C and place the test directly after that in the Premi®Test block heater or water bath with a temperature of 64°C. The test will be read after 3 hours.

Test format.

Premi®Test-egg is supplied in polystyrene boxes in quantities of 25 or 100 ampoules.

Shelf life

The test ampoules should be kept in a dark place at a constant temperature between 6 and 15 °C. The shelf-life will under these conditions is minimum 3 months.

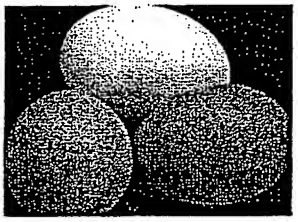
DSM Food Specialties
Meat Ingredients
P.O. box 1, 2600 MA Delft,
The Netherlands
tel: +31 15 2794119, fax: +31 15 2793480

February 2000

DSM

Premi®Test-egg

Broad spectrum screening test for detection of antimicrobial compounds in eggs.



Introduction

Medication of poultry administered through feed, will lead to residues in the chicken meat and in the eggs for a certain period of time.
Antibiotics are applied as medication, or as growth promotors.
Growing concerns over health related issues associated with the intake of these residues and over drug resistant bacteria have led to an increased demand for reliable test methods.
EU legislation specifies maximum residue levels for antibiotics in various products.
The Premi®Test-egg is the latest development in the microbial screening tests, which will enable you to detect the presence of antibiotic compounds in eggs.

What is Premi®Test-egg ?

Premi®Test-egg is a broad spectrum-screening test that within 3 hours detects the majority of anti-microbial compounds. It is developed based on decades of experience in the field of detection of antibiotics and sulphonamides in milk and other food products.
The test is cost effective and simple to perform.
Within 3 hours the results are available.
The test is equally suitable for testing a single sample as well as hundreds of eggs simultaneously.

Why a broad spectrum screening test?

In order to prevent that any eggs containing antibiotics enter the food chain, a fast, sensitive, reliable and easy-to-use test covering a broad range of restricted substances is needed.
Where conventional microbiological test methods generally require overnight incubation, Premi®Test-egg gives a reliable result within 3 hours. This allows you to take quick decisions on further processing of the eggs.

Premi®Test-egg is a sensitive screening test which detects a large number of antibiotics.
Unlike other tests, a negative Premi®Test-egg result reliably
indicates the absence of the most relevant antibiotics in the egg sample (see table 1).

Table 1: Sensitivity of Premi®Test-egg

Antibiotic	Limit of detection.*
B-lactams	
Penicillin	2
Amoxicillin	5
Ampicillin	4
Cloxacillin	20 – 30
Tetracyclins	
Tetracyclin	200
Oxytetracyclin	200 – 400
Doxycyclin	200
Sulfonamides	
Sulfadimidin	25 - 50
Sulfadiazin	25 - 50
Macrolides	
Tylosin	25 – 50
Erythromycin	25 - 50
Spiramycin	400
Cephalosporins	
Ceftiofur	200 – 400
Aminoglycosides	
Gentamycin	200
Streptomycin	500

* Concentration given in parts per million. (µg. /kg.)

Reading the test

A yellow colour indicates a negative sample (anti-microbial compounds below the limit of detection).

DSM Food Specialties
Meat Ingredients
P.O. box 1, 2600 MA Delft,
The Netherlands
tel: +31 15 2794119, fax: +31 15 2793480

February 2000

DSM

DSMProduct

Premi®Test sample procedure for eggs

Background

Using egg fluids in a microbial inhibition test may result in false positive results due to the presence of several naturally occurring inhibitors in egg yolk.
To prevent these inhibitors interfering with the test result a special protocol is required to use the Premi®Test for the detection of antibiotic residues in eggs.
Therefore DSM has developed a proprietary technology. This patented technology is described in this technical bulletin.
The influence of naturally occurring inhibitors can easily be prevented by inactivating the proteinaceous factors in eggs through a short heat pre-treatment step of the egg fluid.

Sample preparation method

- Wash hands before use and make sure to use a clean working surface.
- Make a hole of approximately 1-2 cm in the egg.
- Prick into the egg yolk, so the yolk will flow out of the egg easier with the egg white.
- Place the egg with the hole down on a clean bottle.
- After the egg is empty, close the bottle.
- Homogenize the egg fluid by shaking the bottle for several seconds.

Instructions for using Premi®Test

- Remove the aluminum foil carefully from the ampoule(s).
- Use a clean tip on the syringe.
- Transfer 100 µl of homogenized egg fluid to the agar in the ampoule, by pressing the syringe once and releasing it. It will automatically take up the required volume.
- Close the ampoules with the plastic foil supplied with the kit.
- Place the ampoule(s) in a water bath at 80°C for 10 minutes.
- After this heat pre-treatment, incubate the test in the DSM heating block incubator or in a water bath at 64°C (± 0,5 °C). Hereafter follow the procedure indicated in the manual of the Premi®Test.
- Incubate the sample for approx. three hours and check the color.
- Use a negative sample as control.

Reading the test results

- When the negative control changes color from purple to yellow (approx. 3 hours), the results can be read.
- Read the results from the bottom 2/3 part of the ampoule.
- A clear color change purple to yellow indicates that the antimicrobial compounds are below the Premi®Test detection limits.
- A purple color indicates the presence of antibiotics at or above the detection limits of the Premi®Test.

Version: Tib ptest samp egg 0301
Date of issue: July 12, 2005

DSM Premi®Test B.V., P.O. Box 6500,
6401 JH Heerlen, The Netherlands, Tel. +31 (0)45 5782136
Fax. +31 (0)45 5782530, Internet site: www.premitest.com